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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,557	BANDMAN ET AL.	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *7,9,12-14 and 16-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,10,11 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/14/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 34 (claims3-6, 8, 10-11) on 5/14/2004 is acknowledged. The traversal is on the grounds that the restriction is improper since unity of invention must be applied in the national stage applications. Applicants' arguments with respect to examination of claims 1, 2 and 15 drawn to a polypeptide of SEQ ID NO:9 with the polynucleotide of SEQ ID NO:34 are persuasive and claims 1, 2, 15 will be examined with the polynucleotide of claims 3-6, 8, 10-11. However, with respect to claim 9 (drawn to an antibody which binds the polypeptide of claim 1) and claims 18, 21 (drawn to a composition comprising an agonist or an antagonist of the polypeptide of claim 1), Applicants arguments are not found to be persuasive because the PCT rules define a special technical feature as a feature, which defines a contribution over the prior art. The first claimed invention drawn to a polypeptide of SEQ ID NO:9 and polynucleotide encoding such fails to recite such a feature, since a single amino acid of the prior art (the 35-40 kD proteins disclosed in WO 92/05256) meets this limitation of a "biologically active fragment" in the absence of the recitation in the claims of a biological activity for the claimed fragment. Since the first claimed invention lacks a special technical feature, the other claimed inventions cannot share a special technical feature with the first claimed invention.

The test for propriety of restriction is not whether the inventions are related but rather whether they are distinct and whether it would impose a burden on the examiner to search and examine multiple inventions in a single invention. The antibodies, agonists and antagonists are different products which are independent and distinct, each from the

other, which possess characteristic differences in structure and each has an independent utility, that is distinct for each invention which cannot be exchanged.

Lastly the inventions are distinct because a search of the literature for the polypeptide of SEQ ID NO:9, would not be expected to reveal art for the antibodies, agonists and antagonists, which searches are extensive requiring separate searches, which would be unduly burdensome.

The Groups as delineated in the restriction requirement (4/21/2004) are patentably distinct one from the other such that each invention could, by itself, in principle, support its own separate patent (as shown by the arguments put forth in the written restriction requirement).

The requirement is still deemed proper and is therefore made FINAL.

Claims 7, 9, 12-14, 16-22 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Furthermore, Applicants request rejoinder of the subject matter of method claims 12-14, 16-17, 19-20, 22-23 (see In re Ochiai (37 USPQ2d 1127 (Fed. Cir. 1995)), in which a new, unobvious material is used in a known process. Ochiai determined that a process was free of the prior art if it employed a product, which was free of the prior art. However, only if the product claims (polynucleotide and polypeptide) are found allowable, the subject matter of the product claims will be rejoined with the process claims if the process claims are of the same scope as the allowable product claims.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly

indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention. It is suggested that the title be amended to recite a nucleic acid encoding the protein.

Claim objections

3. Claim 3 is objected to for the following reason:

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

Claim 3 is improperly dependent on claim 1 because clearly, the product of claim 1 as recited can be obtained from natural sources. Therefore, instant claim 3 does not infringe the polypeptide of claim 1. A proper dependent claim shall not conceivably be infringed by anything, which would not also infringe the basic claim. See MPEP § 608.01(n), "Infringement Test" for dependent claims.

Appropriate correction is requested.

Claim rejections-35 U.S.C. 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8, 10-11, 15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The instant claims are drawn to a nucleic acid encoding a polypeptide and the polypeptide itself, said polypeptide having as yet undetermined function or biological significance. Until some actual and specific significance can be attributed to the protein of SEQ ID NO:9 identified in the specification as having homology to the "Drosophila melanogaster LRR47" (Table 2, page 67), the instant invention is incomplete. The translation product of the claimed protein encoded by SEQ ID NO:34, encodes a "leucine-rich repeat domain" (LRR). "The LRRs are sequence motifs, approximately 22-28 amino acids in length found in proteins with a large variety of functions and cellular. Proteins containing LRRS are thought to be involved in protein-protein interactions." (page 6, lines 26-28). However, the instant specification does not disclose any information regarding functional characteristics or the biological activity of the instantly claimed protein. While the specification on page 6, last para, describes many activities for the instant protein, such as LLRs function in signal transduction and cellular adhesion as well as in protein-protein interactions, there is no guidance given about which specific activity/activities the claimed polypeptide would be likely to have. The specification does not demonstrate that the claimed polypeptide actually displays any of these recited activities. In the absence of knowledge of the specific biological significance of the claimed protein, there is no immediately obvious patentable use for it. Since the instant

specification does not disclose a "real world" use for the nucleic acid encoding the protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 USC § 101 as being useful.

A protein of unknown function would have utility if it can be employed as an indicator of a diseased state or of the presence of a disorder. The only disclosed function for the protein of the instant invention is that it contains the LRR domain (Table 2, page 67). Applicant is only required to identify one substantial credible utility and the employment of this protein only as the subject of further research does not satisfy the utility requirement of 35 U.S.C. § 101 because the courts have interpreted this statute as requiring an invention to have "substantial utility" "where specific benefit exists in currently available form".

Applicants disclose in the specification that the claimed protein contains the LRR domain (Table 2, page 67). The state of the art is such that functional information can be automatically derived from structural information only to a limited extent, (see Sklonick et al, Nature Biotechnology, Vol.18, No.3, pages 283-287, especially page 286, middle of column 1). Sklonick et al also state that knowledge of the overall structure or domain family is still not enough to confidently assign function to a protein. Therefore, there is little doubt that, after further characterization, the protein is found to be member of the LRR protein family, the claimed protein would have a specific, substantial and credible utility. However, further characterization is part of the invention and until it had been undertaken, the claimed invention is not supported by a specific asserted utility or a well established utility. The claimed invention is directed to a polypeptide of as yet undetermined function or biological significance. Thus, since there is no demonstrated

biological activity disclosed for the protein encoded by the claimed nucleic acid, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

Claims 1-6, 8, 10-11 and 15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification does not disclose a biological activity for the claimed protein, therefore, there is no specific and substantial asserted utility or well established for the claimed protein. The fact that the claimed nucleic acid encodes a protein that has the LRR domain is not sufficient to establish a specific and substantially asserted utility or a well established utility for it.

Should Applicants establish an activity for the polypeptide of SEQ ID NO: 9 encoded by the polynucleotide of SEQ ID NO: 34, the instant specification would still fail to adequately describe and enable an isolated protein that is at least 90% identical to the polypeptide of SEQ ID NO:9. Applicants do not teach which regions of said polypeptide are critical to encode a functional polypeptide. The specification does not provide the requisite examples nor a representative number of different sequences that would allow the skilled artisan to produce a polypeptide having at least 90% sequence identity to SEQ ID NO:9, nor does the disclosure provide criteria that explicitly enable such critical features. There is no guidance in the specification as to how one of ordinary skill in the art would generate a polypeptide, other than that exemplified. The issue here is the breadth of the claims in light of the predictability of the art as determined by the

number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record.

In summary, the amount of experimentation required for one of ordinary skill in the art to use the claimed invention, an isolated polypeptide that is at least 90% identical to the polypeptide of SEQ ID NO:9, would be undue. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those nucleotide sequences of the disclosed naturally-occurring nucleic acid encoding the claimed polypeptide, which are required for functional and structural integrity of the claimed polypeptide. It is this additional characterization of the disclosed polypeptide that is required in order to obtain the functional and structural data needed to permit one to produce a polypeptide, which meets both the structural and functional requirements of the instant claim that constitutes undue experimentation.

Claim rejections-35 U.S.C. 112, first paragraph, written description

5a. Claims 1-3, 5-6, 8, 10-11, 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID NO:34 and equivalent degenerative codon sequences thereof and therefore the written description is not commensurate in scope with the claim drawn to "naturally occurring" polynucleotide variants as recited in claim 10(b) or "naturally occurring" polypeptide variants as recited in claim 1(b).

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Reiger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined. With the exception of SEQ ID NO:34, the skilled artisan cannot envision the detailed structure of the encompassed polynucleotides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity does not provide an adequate written

description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Support for allelic variants is provided in the specification on page 12, lines 28-34. However, no disclosure, beyond the mere mention of variants is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only an isolated nucleic acid molecule comprising a nucleic acid sequence consisting of SEQ ID NO:34 and equivalent degenerative codon sequences thereof, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

5b. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 11 recites "comprising at least 60 contiguous nucleotides" and encompasses a genus of nucleic acid molecules comprise only portions of the full-length sequence of SEQ ID NO:34 as well as variants having one or more nucleotide deletions,

insertions and/or additions made to SEQ ID NO: 34. The specification and claim do not indicate what are the distinguishing attributes shared by the members of the genus for which the common portion is responsible for functional activity. The specification and claim do not place any limit on the number of nucleotides that may be added to the portions since the claim is not limited to the full-length SEQ ID NO:34. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claim do not provide a written description as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the polynucleotide class are missing from the disclosure. No common structural and functional attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, nucleic acid molecules comprising at least 60 contiguous nucleotides of SEQ ID NO:34 alone are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus.

Claim rejections-35 U.S.C. 112, first paragraph, scope of enablement

6a. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a host cell in culture comprising a polynucleotide with the sequence as set forth in SEQ ID NO: 34, does not reasonably provide

enablement for *in vivo* transfection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification discloses that the nucleic acids of the current invention can be expressed in a wide variety of host cell types, including cells within a host animal (page 32, 24). However, there are no actual or prophetic examples that disclose how to make or use host cells that comprise a DNA sequence as set forth in SEQ ID NO: 34 in an animal. The Examiner cites Eck & Wilson (page 8 1, column 2, second paragraph to page 82, column 1, second paragraph) who report that numerous factors complicate *in vivo* gene expression which have not been shown to be overcome by routine experimentation. These include, the fate of the DNA vector itself (volume distribution, rate of clearance into the tissues, etc.), the *in vivo* consequences of altered gene expression and protein function, the fraction of vector taken up by the target cell population, the trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA produced, the amount and stability of the protein produced, and the protein's compartmentalization within the cell, or its secretory fate, once produced. Since the instant disclosure does not address any of the methods necessary to make a host cell in an animal, which comprises the polynucleotide of interest, the claims as written are not enabled. This rejection could be overcome by addition of the limitation wherein the host cells are "isolated".

6b. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide comprising the nucleotide sequence set forth in SEQ ID NO:34, does not reasonably provide enablement for a

polynucleotide comprising at least 60 nucleotides of SEQ ID NO:34 as recited in claim 11. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claimed genus of polynucleotide molecules encompasses variants that do not share activity of the polypeptide, however, the specification does not teach how to make a polynucleotide molecule encoding a polypeptide having an amino acid sequence less than SEQ ID NO:9. The specification only enables a nucleic acid molecule encoding a protein of amino acid sequence set forth in SEQ ID NO:9, and is not enabled for a nucleic acid molecule of nucleotide sequence anything less than what is disclosed in SEQ ID NO:34.

The issue in the instant case is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. The recitation of "at least 60 contiguous nucleotides..." in claim 11, is not a sufficient structural limitation and broadly encompasses any nucleic acid molecule comprising 60 contiguous nucleotide sequences recited in the claims. Because of the presence of the term "comprising" in claim 11, the claim encompasses over 5×10^{100} embodiments.

Furthermore, Applicants have not taught how to make the instant nucleic acid molecules with the stretch of 60 contiguous nucleotides as recited in claim 11. The instant claims are not limited to naturally-occurring compounds and the instant specification does not provide a description of a repeatable process of producing a nucleic acid molecule as claimed.

6c. Claims 1, 3-6, 8, 10-11, 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a polypeptide comprising the amino acid sequence set forth in SEQ ID NO:9, does not reasonably provide enablement for an isolated polynucleotide "...having at least 90% sequence identity to SEQ ID NO:34" or an isolated polypeptide "...having at least 90% identity to SEQ ID NO:9". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 1, for example, is overly broad in the recitation of "at least 90% identical to an amino acid sequence" since no guidance is provided as to which of the myriad of polypeptide species encompassed by the claim will retain the desired characteristics of the polypeptide. Applicants disclose that variants of the polynucleotide can be generated by conservative or nonconservative changes, allelic, splice species or polymorphic variants, without disclosing any actual or prophetic examples on expected performance parameters of any of the possible muteins of SEQ ID NO:9 (pages 12-13). There is no guidance provided in the specification as to how one of ordinary skill in the art would generate a nucleic acid sequence encoding a polypeptide other than that exemplified in the specification. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the

invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Given the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention.

Claim rejections-35 USC § 112, second paragraph

7. Claims 1-6, 8, 10-11, 15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 4, 10, are vague and indefinite because they recite non-elected subject matter. Appropriate correction to recite only the elected polypeptide of SEQ ID NO:9 and the elected polynucleotide of SEQ ID NO:34 is requested.

Claims 1, 10 are indefinite in the recitation of the term "naturally occurring". It is unclear whether this term imposes a required limitation on the claims, such that it only encompasses, for example, nucleic acid molecules amplified from cDNA or all nucleic acid molecules that encode the polypeptide. Therefore, the metes and bounds of the claim are unclear.

Claims 1 and 10 are rejected as vague and indefinite for reciting "immunogenic fragment". It is unclear what the metes and bounds of this term are. It is suggested that

the claim be amended to incorporate the size of the specific immunogenic fragments supported by the specification.

Claim 1 is vague and indefinite because it recites "biologically active" fragment. The term "biologically active" is not defined by the claim, and the specification on page 14, give no definition of what this activity is. Various biological activities can be attributed to a peptide. For example, "activity" could constitute transportation throughout a cell, alteration of tertiary structure due to changes in pH, ligand binding, or modulation of second messenger effect, etc. 'Activity' could also be referring to the ability of the fragment to stimulate antibody production.

Claims 3, 5-6, 8, 11, 15 are rejected as vague and indefinite insofar as they depend on the above rejected claims for their limitations.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-6, 8, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ntwasa et al (1994).

The reference discloses a cDNA encoding a Drosophila LRR47 protein (see abstract; page 182, Figure 1). The nucleic acid encoding the LRR47 was cloned into a vector and host cells were transformed with the vector to obtain the recombinant LLR47 protein in a pharmaceutically acceptable carrier (page 183, column 1, second full para).

A "biologically active fragment" of the LLR47 protein would potentially be any amino acid since the claims fail to recite and the instant specification fails to disclose the biological activity of the claimed protein of the instant invention. Therefore, the cDNA and polypeptide disclosed in the reference meets the limitations of claims 1, 3, 5-6, 8, 15.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
June 28, 2004